



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	00-0050	2575
40158	7590	04/19/2007	EXAMINER	
WOODS FULLER SHULTZ & SMITH P.C. ATTN: JEFFREY A. PROEHL P.O. BOX 5027 SIOUX FALLS, SD 57117			STIGELL, THEODORE J	
		ART UNIT	PAPER NUMBER	
		3763		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	04/19/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/633,573	ASFORA, WILSON T.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12,33-35,37-39 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12,33-35,37-39 and 42-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendment

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

Claims 1-35, 37-39, and 42-48 are objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-9, 33, 37, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Swann et al. (4,646,752). Swann discloses a port device and kit comprising a tubular portion (14) including self-tapping threads for insertion into an opening, a pair of wings (21) for facilitating rotation, and retaining means (18) that are capable of engaging an interior surface of a flexible wall, wherein the retaining means facilitates sliding insertion of the distal end of the conduit, wherein the wings are mounted on the tubular portion between the distal and proximal ends of the device, and further including a tubular conduit (7), a drill bit (32), and stop collar (33).

Claims 1-6, 9, 11, 33-35, 37-39, 42, and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Akers (3,650,551). Akers discloses a port device (14) comprising a tubular portion (21) including self-tapping threads (18) for insertion into an opening, a pair of wings (24) for facilitating rotation, and retaining means (26) including up to three frustoconical barbs that are capable of engaging an interior surface

Art Unit: 3763

of a flexible wall, wherein the retaining means facilitates sliding insertion of the distal end of the conduit, wherein the wings are mounted on the tubular portion between the distal and proximal ends of the device

Claims 1-3, 6, 9, 11, and 46-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleckenstein (6,454,774). Fleckenstein discloses a port device and kit comprising a tubular portion (7) including self-tapping threads for insertion into an opening, a pair of wings (9) for facilitating rotation, and retaining means (threads of 8) that are capable of engaging an interior surface of a flexible wall, wherein the wings are mounted on the tubular portion between the distal and proximal ends of the device, and further including a tubular conduit (11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752) in view of Lake (US 3,766,910 A). Swann discloses the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other. Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration. It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Swann et al., by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752) in view of Baudino (US 6,110,155 A). Swann et al. disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition. Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3,

lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end. It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al., by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A). Swann et al. in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb. McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb. It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view Lake (US 3,766,910 A), further in view of Baudino (US 6,110,155 A), and further in view of McNeil et al. (US 4,828,546 A).

Swann et al. disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Swann et al., by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Swann et al., and further in view of Lake disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32)

are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al., and further in view of Lake by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Swann et al., further in view of Lake, and still further in view of Baudino disclose the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al., further in view of Lake and still further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Response to Arguments

Applicant's arguments with respect to claims 1-12,33-35,37-39 and 42-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Theodore J. Stigell


